
Milk Labeling Work Group 2008

Summary Report

Elisha Modisett
Indiana State Department of
Agriculture



Executive Summary

In November 5, 1993, the US Food and Drug Administration (FDA) approved the use of the animal drug recombinant bovine somatotropin (rbST) in lactating dairy cows to increase the production of marketable milk.¹ FDA approved the product because the agency determined that “after a thorough review that rbST is safe and effective for dairy cows, that milk from rbST-treated cows is safe for human consumption, and that production and use of the product does not have a significant impact on the environment.”²

Since then many studies and arguments have been made whether this claim still holds true. As a result, some dairy processors now market “rbST-free” milk for consumers. The issue now raised is the truthfulness of the statement on milk labels and whether the claim is misleading. Congress dictates that a food is misbranded if a statement on the label or in its labeling is false or misleading under section 403(a) of the Interstate Commerce Act. In addition, a label is also misleading if there is a presence or absence of information on the label under section 201(n). Each state is delegated authority in regulating the labels based on these statutes.

FDA issued a document in February, 1994 to provide guidance to states on what milk labeling standards are appropriate concerning statements regarding the use of rbST. No updates have been issued by the FDA since then, even though states have been struggling with what labeling requirements are acceptable as the consumer market for rbST-free milk has increased over the years.

Indiana has not been sheltered from this debate. Consumer groups, milk processors and dairy farmers all have stakes in the issue of milk labeling. Given that the law regarding milk labeling is authored by Congress and enforced by the FDA, it is recommended that the Indiana General Assembly pass a resolution urging the FDA to revisit the milk labeling guidelines so as to not create a patchwork of regulations from state to state, but to have uniform direction nationally. The dairy industry is a vital component to Indiana’s agricultural economy, but the state alone cannot address this important issue by itself.

¹ 58 FR 59946, Nov. 12, 1993.

² 59 FR 6279, Feb. 10, 1994.

Background

In the 2007 legislative session, Representative Bill Friend introduced HB 1300 in the House Agriculture and Rural Development Committee. The bill sought to amend the law so that dairy products are considered misbranded if the labeling contains compositional claims that cannot be confirmed through laboratory analysis or can only be supported by sworn statements, affidavits, or testimonials. The legislation passed the House committee but it did not make it through the Senate.

The issue revolves around the use of recombinant bovine somatotropin (rbST), a commercially produced protein hormone that stimulates milk production. The use of rbST, approved by the FDA in 1993, cannot be detected through laboratory testing because bST is a naturally occurring protein hormone produced in lactating dairy cows. The supplemental rbST helps increase the conversion of feed to milk in the cow but does not result in more bST found in the milk³. Dairy processors can voluntarily inform consumers that their milk product does not use milk from cows treated with rbST, provided that the statements are truthful and not misleading. Therefore, those claims must be accompanied with information that puts the statement in the proper context.⁴

Following the end of session, Representative Friend wrote a letter to the Lieutenant Governor Becky Skillman, who also serves as the Secretary of Agriculture for the Indiana State Department of Agriculture (ISDA). He requested that ISDA serve as a facilitator to further study the issue amongst interested parties and agencies. Elisha Modisett, Legislative Liaison for ISDA, headed the working group study for the department.

ISDA began contacting those individuals and organizations that had shown interest in the issue when the legislation was moving through the General Assembly. They also enlisted the help of the Indiana Board of Animal Health (BOAH) to try and identify the groups who might want to participate in the informal study of the issue. BOAH is the state agency who maintains regulatory authority over milk labeling. One of their roles is “the prevention, detection, control and eradication of infectious, contagious and communicable diseases affecting the health of animals...and processing and distribution of products derived from animals to control health hazards that may threaten public health” (IC 15-17-3-13).

The list of individuals and organizations who expressed interest in participating in the working group came to approximately forty people.⁵ Two working group meetings were held. The first meeting was June 26, 2008. The second meeting was held on August 22, 2008.

³ Scott, Donna “Cornell University – bST Fact Sheet”, U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition FDA Prime Connection, June 9, 1995, <<http://www.cfsan.fda.gov/~ear/CORBST.html>>

⁴ 59 FR 6279, Feb. 10, 1994.

⁵ A list of the individuals who participated in the working group is included in Appendix A.

Meeting #1

The first meeting was held on June 26, 2008 at the Indiana Government Center South. Twenty-two people were in attendance. Indiana Board of Animal Health made a presentation on Indiana's role in milk labeling and provided the FDA guidance document on the labeling policy concerning the use of rbST.⁶

BOAH approves the wording on milk labels based on Indiana law. That law is derived from the FDA rules and the Pasteurized Milk Ordinance. IC 15-18-1-15 states that:

“a person may not manufacture, sell, exchange, or have in the person's possession with intent to sell or exchange, any milk or milk product that:

- (1) does not conform to at least the minimum standards established and approved by the board; or
- (2) is packaged in a container or wrapping with labeling that has not been approved by the board.”

The FDA guidance document was issued on February 7, 1994 to provide states and industry groups with guidelines regarding the labeling of milk that has not been treated with rbST to prevent misleading statements. FDA relies on state agencies for compliance to ensure claims are truthful and not misleading. Because bST naturally occurs in cows, a label cannot claim to be “bST-free”. However, companies that do not use milk from cows treated with rbST may voluntarily inform consumers on its labels of this fact. A label can state that the milk is “from cows not treated with rbST” but must be accompanied with a qualifying statement so as to not imply that milk from untreated cows is safer or higher quality than milk from cows that are treated with rbST. To not qualify the statement would be considered untruthful and misleading.

Therefore, FDA said that such statements can be accompanied with information that puts the statement in proper context. A suggested statement would be “*no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows.*” This is the qualifying statement to which Indiana adheres. FDA concluded that states should evaluate any labeling statement about rbST in the context of the complete label of the product, as well as of any advertising for the product.

At the end of BOAH's presentation, Ms. Modisett asked that anyone who wished to submit comments regarding Indiana's law on milk labeling to send those to her by August 1. The comments would be compiled and prepared for the next meeting. Approximately 500 comments were received.

⁶ A copy of the PowerPoint presentation and FDA document are included in Appendix B.

Meeting #2

The second meeting took place on August 22, 2008 at the Indiana Government Center South. Twelve members of the audience made public comments.

Grant Monahan, representing the Midwest Dairy Foods Association, stated that he would like to see no changes made to Indiana's current law and regulations. He noted that a national approach would be the only way to address the issue. If Indiana adopts its own labeling standard that is different from other states, it would hurt Indiana farmers.

Steve Bonney, executive director of Sustainable Earth, said that he wants no change to Indiana's law. The way it is currently written gives consumers a choice in knowing which products they are buying. He stated that they are not opposed to the use of rbST but consumers have the right to know. He suggests letting the market place be the determining factor.

Julia Vaughn, Citizens Action Coalition, suggested keeping the current law as is. She stated that prohibiting the current label is a contraction to freedom of speech. Consumers have the right to know because the use of rbST remains controversial.

Kevin Fisk is the director of state affairs for the Grocers Manufacturers Association. They represent many of the national brands. His organization is opposed to any changes on the state level for three reasons: (1) making changes to packaging and labeling will be costly and inconvenient to the industry because labeling space is limited on products; (2) it will interfere with interstate commerce; and (3) they question whether it is a restriction to commercial free speech. Grocers Manufacturers Association supports asking the FDA for guidance.

Tamilee Nennich Ph.D., Department of Animal Sciences at Purdue University, cited that the use of rbST cannot be proven or tested. Posilac[®], the commercial name of rbST first produced by Monsanto and now owned by Elanco, has been proven safe by the FDA in 1993 and again in 1999. Ms. Nennich explained the science behind bST and rbST, giving an overview of the hormone's composition and its effects on cows and humans. She said that bST and rbST are entirely digested into amino acids in the human digestive tract.

Sarah Alexander is the senior food organizer for Food and Water Watch, a consumer advocacy group based in Washington DC. Ms. Alexander said the organization would like to see no changes made to Indiana's law. Instead the change should be with the milk pricing structure. The current label regulations allow consumers to know how their milk is produced. She cited eight other states who have acted on milk labeling changes at some level and each state was threatened with a lawsuit or were sued for the changes.

Bob Kraft, Indiana Farm Bureau, stated that there is no science available to differentiate between the milks. The issue is not with the use of rbST but with the truth in labeling. The disclaimer on the label is too small or located inconspicuously which results in misleading consumers who are not aware of the difference. This is an interstate commerce issue that really needs to be addressed by the FDA on a national level. Mr. Kraft proposed instead that Indiana pass a resolution that urges the FDA to examine their labeling guidelines in light of new marketing that is taking place in the dairy industry. American Farm Bureau Association found that restricting the use of rbST hurts smaller producers up to \$400 per cow because of lower milk production levels.

Barbara Sha Cox, part of a grassroots organization, testified that she is worried about the impact rbST has on humans. She believes that the quality of milk is less and that is a more important issue than the quantity of milk produced. Consumers should have a right to know how their milk is produced.

LuAnn Troxel, dairy farmer from LaPorte County, noted that the labels are confusing to consumers who do not understand the issue and use of rbST. She noted that a negative label can lead to negative impacts on food production. Small-production farmers need to use Posilac® in order to produce the amount of milk needed to meet consumer demand.

Steve Harrold, Caito Foods representing Organic Trade Association (OTA), discussed organic labeling and the certification process. Organic foods are verified through USDA-accredited third party inspections and certification. State regulation of labeling on organic products is prohibited unless approved by USDA. OTA opposes any proposed regulations on dairy labeling as it applies to organic dairy products and the restriction regarding the use of rbST. OTA also recommends that certified organic dairy products be exempted from any proposed rule. A “one size fits all” dairy labeling rule will likely conflict with the Organic Foods Production Act of 1990.

Rick North, Oregon Physicians for Social Responsibility, would like to see no change to Indiana’s labeling law. His organization is trying to change the labeling guidelines through the FDA. They disagree with the disclaimer and note that absent labeling exists in other areas. Mr. North agreed with the argument that a “hormone-free” label is misleading because all milk contains hormones. The organization is against the use of rbST though because not enough time has passed to know if it does or does not have a negative impact on humans.

Susan Troyer, Michigan Milk Producers Association and Indiana dairy farmer, stated that consumers have the right to know what is in their milk but they also have a right to affordable milk that is safe and nutritious. Allowing processors to force farmers to sign a legal affidavit that they will not use rbST takes away the cheapest option of conventionally produced milk. She noted that both “rbST-free” and organic milks are no different in their nutritional value or safety than that of conventional milk, but they are different in price. The use of rbST also reduces the carbon footprint because fewer cows are needed to produce the same amount of milk.

Conclusion

There were two main remarks gathered from the comments ISDA received. One was that Indiana should leave its current rules on milk labeling as is. The reasoning was that it allows consumers the right to know how their milk and dairy products are produced. In addition, the current rules allow for simplified shipment of Indiana's dairy products, because the state does not require more stringent requirements of its labels compared to other states. One label can be used for interstate shipments.

The other comment was that the labels claiming "rbST-free" should not be misleading. There are viewpoints that the disclaimer of its use is not prominent enough on the label. In addition the claim gives consumers a false sense that milk produced without rbST is better than conventional milk, especially if the qualifying statement is not visible enough on the packaging to educate the consumer on the difference.

The federal Interstate Commerce Act is a controlling component to the milk labeling regulations in the United States. Although each state is responsible for enforcing the law and regulations of the labeling requirements and is given leeway to expand upon them, that discretion can result in a patchwork of rules from state to state which ultimately may run in contradiction with the Interstate Commerce Act that it enacted it.

Therefore, in serving the best interest for the State, it is recommended that the Indiana General Assembly pass a joint resolution urging the federal Food and Drug Administration to revisit its labeling guidelines. FDA needs to address these contemporary issues that have surfaced in various states surrounding the truthfulness of dairy labels. Indiana will benefit most from receiving guidance from the federal level rather than try to resolve the debate on its own.

Appendix A

(These are only the names of those individuals who wished to be notified of the working group activities. It does not include the names of all those who submitted comments.)

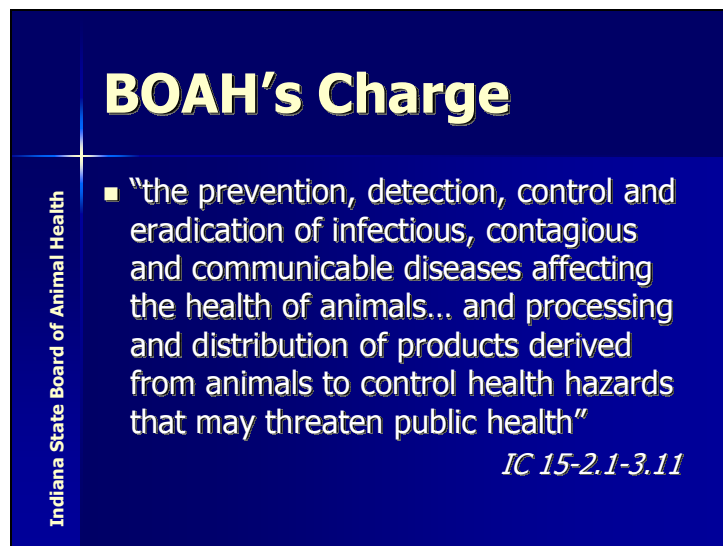
Kristin Mullins	<i>Midwest Dairy Foods Assoc.</i>	Kevin Fisk	<i>Grocer's Manufacturers Assoc.</i>
Grant Monahan	<i>Indiana Retailers Council</i>	Adam Moody	<i>Moody Meats</i>
Cress Hizer	<i>Nestle</i>	Julia Vaughn	<i>Citizens Action Coalition</i>
Doug Lehman	<i>IN Prof. Dairy Producers</i>	Troy Snider	<i>Dairy Producer</i>
LuAnn Troxel	<i>IN Prof. Dairy Producers</i>	Bill Beranek	<i>Indiana Environmental Institute</i>
Susan Troyer	<i>Dairy Producer</i>	Mark Armfelt	<i>Monsanto</i>
Bob Kraft	<i>Indiana Farm Bureau</i>	John Barnett	<i>Bose Public Affairs</i>
Gary Haynes	<i>State Board of Animal Health</i>	Nicole Upano	<i>Indiana Retailers Council</i>
Dr. Thomas Kuhn	<i>State Veterinarian Assoc.</i>	Laura Schenkel	<i>Baker & Daniels</i>
Gary Corbett	<i>Fair Oaks Dairy</i>	Rob Lagerlof	<i>Prairie Farms</i>
Dave Tierney	<i>Monsanto</i>	Greg Janzow	<i>Smith Dairy</i>
Pat McGuffey	<i>Monsanto</i>	John Newsom	<i>Indiana Farm Bureau</i>
John Baugh	<i>Purdue University</i>	Barbara Sha Cox	<i>Grassroots group</i>
Julia Wickard	<i>Ind. Beef Cattle Assoc.</i>	Mathew Norris	<i>Wal-mart</i>
Sarah Alexander	<i>Food & Water Watch</i>	Dan Belk	<i>Foremost Farms USA Dairy Co-op</i>
Helen Piotter	<i>Dean Foods</i>	Gregg Elliott	<i>Foremost Farms USA Dairy Co-op</i>
Chuck McQuaig	<i>Prairie Farms</i>	Will Telligman	<i>International Dairy Foods Assoc.</i>
Jim Benham	<i>Indiana Farmers Union</i>	Jerry Slominski	<i>International Dairy Foods Assoc.</i>
Michael Prete	<i>Traders Point Creamery</i>	Tom Langan	<i>Unilever</i>
Brendon Cull	<i>Kroger</i>	Steve Bonney	<i>Sustainable Earth</i>
Dave Hassler	<i>Oberweis Dairy</i>	Dave Gagnon	<i>Organic Trade Association</i>
John Keeler	<i>Kraft Foods</i>		

Appendix B – BOAH PowerPoint and FDA Guidance Document

Slide 1



Slide 2



Indiana State Board of Animal Health	<h2>BOAH's Mission</h2>
	<ul style="list-style-type: none">■ Animal Health<ul style="list-style-type: none">■ Pseudorabies, tuberculosis, scrapie, rabies■ Food Safety<ul style="list-style-type: none">■ Meat & Poultry, Dairy Inspection■ Emergency Preparedness<ul style="list-style-type: none">■ SAVE, Animal Issues in Disaster, bioterrorism

Indiana State Board of Animal Health	<h2>BOAH Role in Labeling</h2>
	<p>A person may not manufacture, sell, exchange, or have in the person's possession with intent to sell or exchange, any milk or milk product that:</p> <ul style="list-style-type: none">- does not conform to at least the minimum standards established by BOAH; and- is packaged in a container or wrapping with labeling that has not been approved by BOAH <p><i>-IC 15-2.1-23-6.3</i></p>

Indiana State Board of Animal Health	BOAH Role in Labeling
	<ul style="list-style-type: none">■ Approve the wording on labels based on Indiana law<ul style="list-style-type: none">– State law is based upon FDA rules and the Pasteurized Milk Ordinance

Indiana State Board of Animal Health	FDA Guidance
	<ul style="list-style-type: none">■ FDA approved use of rBST, 1993<ul style="list-style-type: none">– found milk from treated cows is safe to consume– no difference in milk composition between treated and non-treated cows<ul style="list-style-type: none">■ no way to test for rBST■ Issued Guidance Document, 1994

Indiana State Board of Animal Health

FDA Guidance

- FDA relies on state agencies for compliance
 - ensure claims are truthful and not misleading
 - substantiate claims (affidavits)
 - verify “certified” programs

FDA Guidance

- Companies that do not use milk from cows treated with rBST may voluntarily inform consumers on labels
 - Statements must be truthful and not misleading

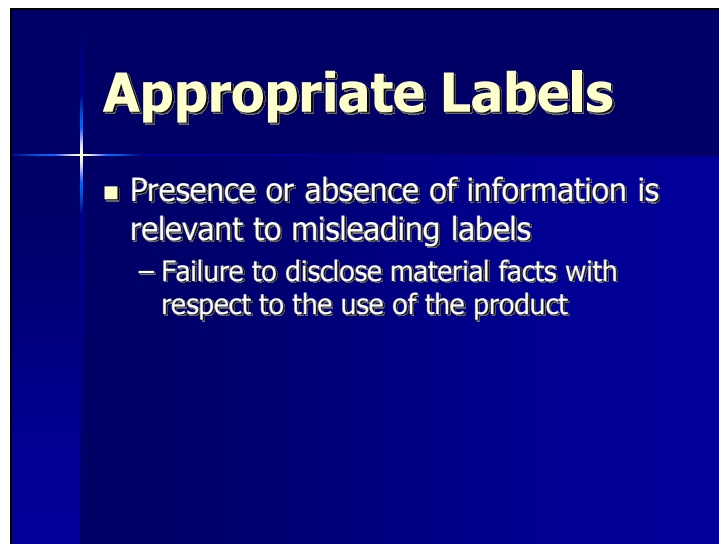
Slide 9

A blue rectangular slide with a white crosshair in the top-left corner. The title "Appropriate Labels" is in bold yellow text at the top. Below it, a single bullet point in white text states: "Food is misbranded if label statements are false or misleading".

Appropriate Labels

- Food is misbranded if label statements are false or misleading

Slide 10

A blue rectangular slide with a white crosshair in the top-left corner. The title "Appropriate Labels" is in bold yellow text at the top. Below it, two bullet points in white text are listed: "Presence or absence of information is relevant to misleading labels" and "Failure to disclose material facts with respect to the use of the product".

Appropriate Labels

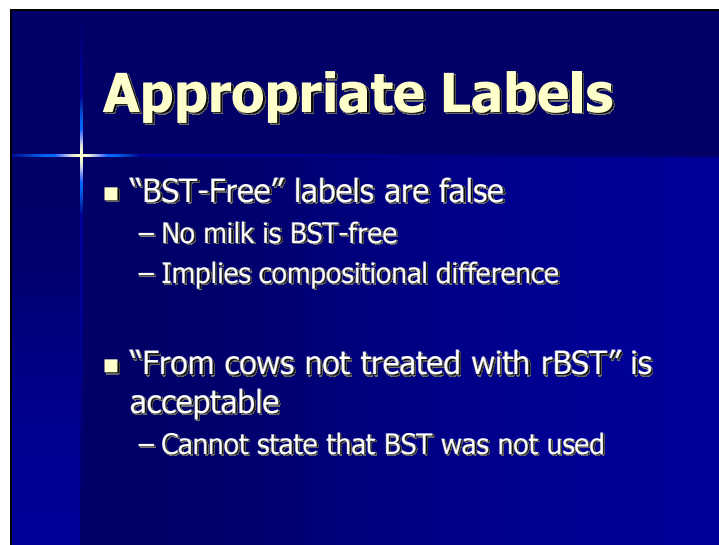
- Presence or absence of information is relevant to misleading labels
 - Failure to disclose material facts with respect to the use of the product



A blue rectangular slide with a white crosshair in the top-left corner. The title "Appropriate Labels" is in bold white text. Below it is a single bullet point in white text.

Appropriate Labels

- Certain statements about rBST use may be misleading unless accompanied by additional information



A blue rectangular slide with a white crosshair in the top-left corner. The title "Appropriate Labels" is in bold white text. Below it are two bullet points in white text, each with a sub-bullet.

Appropriate Labels

- "BST-Free" labels are false
 - No milk is BST-free
 - Implies compositional difference
- "From cows not treated with rBST" is acceptable
 - Cannot state that BST was not used

	<h2>Appropriate Labels</h2>
	<ul style="list-style-type: none">■ Unqualified statements implying milk from untreated cows is safer or higher quality are false/misleading<ul style="list-style-type: none">– Accompanying information can put statements in the proper context– Stated reasons for non-use (other than safety/quality) are allowed

	<h2>Example...</h2>
Indiana State Board of Animal Health	<ul style="list-style-type: none">■ "from cows not treated with rBST" <p><i>To be accompanied by:</i></p> <ul style="list-style-type: none">■ "No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows"

	<h2>FDA Guidance</h2>
	<ul style="list-style-type: none">■ "States should evaluate any labeling statement about rBST in the context of the complete label and all labeling on the product, as well as of any advertising for the product."

	<h2>BOAH Current Position</h2>
Indiana State Board of Animal Health	<ul style="list-style-type: none">■ Currently no additional state regulations beyond FDA guidance■ Strive to meet standards to ensure open borders for interstate trade■ Review of affidavits on file at dairy plants

Indiana State Board of Animal Health

Other States' Rules


- The majority of states currently follow FDA guidelines

Other States' Rules

Web Sites

- Ohio
 - www.ohioagriculture.gov/dairy/dairy_index.stm
- Pennsylvania
 - www.agriculture.state.pa.us/agriculture/cwp/view.asp?a=3&q=126045

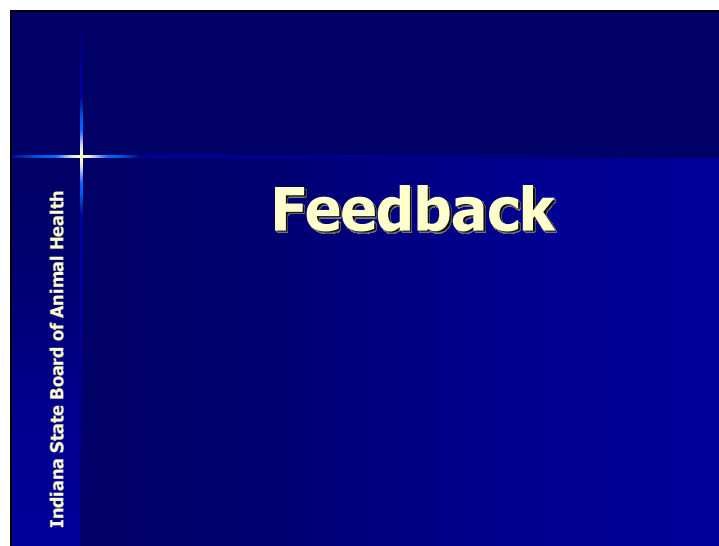
Slide 19

A blue rectangular slide with a dark blue header. The header contains the text "Contact BOAH" in white. Below the header, there is a list of contact information in yellow text, preceded by small square bullet points.

Contact BOAH

- Online: www.boah.in.gov
- Phone: 317/227-0300
- Email: animalhealth@boah.in.gov

Slide 20

A blue rectangular slide with a dark blue header. The header contains the text "Feedback" in yellow. On the left side, there is a vertical white bar with the text "Indiana State Board of Animal Health" in blue. The word "Feedback" is centered on the slide.

Feedback

Indiana State Board of Animal Health

Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated with Recombinant Bovine Somatotropin

[Federal Register: February 10, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D-0025]

Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing interim guidance on the labeling of milk and milk products from cows that have not been treated with recombinant bovine somatotropin. Several States and industry and consumer representatives have requested guidance from FDA on this issue. This interim guidance is intended to respond to these requests.

DATES: Written comments by March 14, 1994.

ADDRESSES: Submit written comments on the interim guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington DC 20204, 202-205-4681.

SUPPLEMENTARY INFORMATION: On November 5, 1993, FDA approved a new animal drug application providing for the subcutaneous use of sterile sometribove zinc suspension (recombinant bovine somatotropin (rbST) or a recombinant bovine growth hormone (rbGH)) in lactating dairy cows to increase the production of marketable milk (58 FR 59946, November 12, 1993). FDA approved the product because the agency had determined after a thorough review that rbST is safe and effective for dairy cows, that milk from rbST-treated cows is safe for human consumption, and that production and use of the product do not have a significant impact on the environment. In addition, the agency found that there was no significant difference between milk from treated and untreated cows

and, therefore, concluded that under the Federal Food, Drug, and Cosmetic Act (the act), the agency did not have the authority in this situation to require special labeling for milk from rbST-treated cows. FDA stated, however, that food companies that do not use milk from cows supplemented with rbST may voluntarily inform consumers of this fact in their product labels or labeling, provided that any statements made are truthful and not misleading. Several States and industry and consumer representatives have asked FDA to provide guidance on the labeling of milk and milk products from cows that have not been treated with rbST.

FDA agrees that, with the expiration of the congressional moratorium on the commercial sale of rbST on February 3, 1994, the issuance of guidance would help prevent false or misleading claims regarding rbST. FDA views this document primarily as guidance to the States as they consider the proper regulation of rbST labeling claims. Given the traditional role of the States in overseeing milk production, the agency intends to rely primarily on the enforcement activities of the interested States to ensure that rbST labeling claims are truthful and not misleading. The agency is available to provide assistance to the States.

The guidance presented here reflects FDA's interpretation of the act and may be relevant to States' interpretation of their own similar statutes. This document does not bind FDA or any State, and it does not create or confer any rights, privileges, benefits, or immunities for or on any persons. Furthermore, this document reflects FDA's current views on this matter. FDA may reconsider its position at a later date in light of any comments it receives on this guidance document.

Interested persons may, on or before March 14, 1994, submit to the Dockets Management Branch (address above) written comments on the interim guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The text of the interim guidance follows:

**Interim Guidance on the Voluntary Labeling of Milk and Milk Products
From Cows That Have Not Been Treated With Recombinant Bovine
Somatotropin**

Appropriate Labeling Statements

At the Federal level, statements about rbST in the labeling of food shipped in interstate commerce would be reviewed under sections 403(a) and 201(n) of the act. Under section 403(a) of the act, a food is misbranded if statements on its label or in its labeling are false or misleading in any particular. Under section 201(n), both the presence and the absence of information are relevant to whether labeling is misleading. That is, labeling may be misleading if it fails to disclose facts that are material in light of representations made about a product or facts that are material with respect to the consequences that may result from use of the product. Thus, certain labeling statements about the use of rbST may be misleading unless they are accompanied by additional information. This guidance is based on the use of the false or misleading standard in the Federal law, which is incorporated in many States'

food and drug laws. States may also have additional authorities that are relevant in regulating such claims.

Because of the presence of natural bST in milk, no milk is ``bST-free,'' and a ``bST-free'' labeling statement would be false. Also, FDA is concerned that the term ``rbST free'' may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would better be formulated as ``from cows not treated with rbST'' or in other similar ways. However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.

FDA believes such misleading implications could best be avoided by the use of accompanying information that puts the statement in a proper context. Proper context could be achieved in a number of different ways. For example, accompanying the statement ``from cows not treated with rbST'' with the statement that ``No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows'' would put the claim in proper context. Proper context could also be achieved by conveying the firm's reasons (other than safety or quality) for choosing not to use milk from cows treated with rbST, as long as the label is truthful and nonmisleading.

States should evaluate any labeling statement about rbST in the context of the complete label and all labeling for the product, as well as of any advertising for the product. Available data on consumers' perceptions of the label statements could also be used to determine whether a statement is misleading.

Substantiation of Labeling Claims

There is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from cows that do not. Therefore, to ensure that claims that milk comes from untreated cows are valid, States could require that firms that use such claims establish a plan and maintain records to substantiate the claims, and make those records available for inspection by regulatory officials. The producer of a product labeled with rbST claims should be able to demonstrate that all milk-derived ingredients in the product are from cows not treated with rbST. Failure to maintain records would make it difficult for a firm to defend itself in the face of circumstantial evidence that it is using rbST or selling milk from treated cows. In some situations (e.g., dairy cooperatives that only process milk from untreated cows), States may decide that affidavits from individual farmers and processors are adequate to document that milk or milk products received by the firm were from untreated cows.

States should consider requiring that firms that use statements indicating that their product is ``certified'' as not from cows treated with rbST be participants in a third party certification program to verify that the cows have not been injected with rbST. States could seek to ensure that certification programs contain the

following elements: Participating dairy herds should consist of animals that have not been supplemented with rbST. The program should be able to track each cow in the herd over time. Milk from non-rbST herds should be kept separate from other milk by a physical segregation, verifiable by a valid paper trail, throughout the transportation and processing steps until the finished milk or dairy product is in final packaged form in a labeled container. The physical handling and recordkeeping provisions of such a program would be necessary not because of any safety concerns about milk from treated cows but to ensure that the labeling of the milk is not false or misleading.

Dated: February 17, 1994,
Michael R. Taylor,
Deputy Commissioner for Policy.
[FR Doc. 94-3214 Filed 2-8-94; 9:27 am]
BILLING CODE 4160-01-F

Elisha Modisett
Legislative Liaison and Policy Analyst
Indiana State Department of Agriculture
emodisett@isda.in.gov

